

## EXPLANATORY MEMORANDUM TO

### THE CONTAMINANTS IN FOOD REGULATIONS (NORTHERN IRELAND) 2013

2013 No. 229

#### 1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Food Standards Agency in Northern Ireland to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.
- 1.2 The Statutory Rule is made under Articles 15(1), 16(1) and (2), 25(1)(a) and 3, 26(3) and 47(2) of the Food Safety (Northern Ireland) Order, as read with paragraph 1A of Schedule 2 to the European Communities Act 1972.

#### 2. Purpose of the Rule

- 2.1 This rule will revoke the Contaminants in Food Regulations (Northern Ireland) 2010<sup>1</sup> and remake them, with necessary amendments in order to provide for the execution and enforcement of certain amended EU requirements, namely Commission Regulations (EU) No. 1258/2011<sup>2</sup> (“the nitrate Regulation”) amending Commission Regulation 1881/2006 as regards maximum levels of nitrate in foodstuffs, Regulation (EU) No. 610/2012<sup>3</sup> (“Regulation 610/2012”) amending Commission Regulation 124/2009 as regards maximum levels for the presence of coccidiostats and histomonostats in food resulting from the unavoidable carry-over of these substances in non-targeted feed and EU Regulations No. 594/2012<sup>4</sup> (as regards maximum levels of the contaminants ochratoxin A, non-dioxin like PCBs), 1058/2012<sup>5</sup> (as regards the maximum levels of aflatoxins in figs) and 1259/2011<sup>6</sup> (as regards maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs).
- 2.2 The rule will also revoke and remake the provisions currently contained in the Erucic Acid in Food Regulations (Northern Ireland) 1977 as amended, thus consolidating these provisions into the proposed Contaminants in Food Regulations (Northern Ireland) 2013 and will revoke the Mineral Hydrocarbons in Food Regulations (Northern Ireland) 1966 in their entirety.

#### 3. Matters of special interest to the Health Committee

- 3.1 None.

#### 4. Legislative Context

- 4.1 The overarching requirements for food contaminants are laid down in Council Regulation 315/93/EEC<sup>7</sup> (“the framework Regulation”) that was adopted on 8<sup>th</sup> February 1993. It defines a food contaminant as any substance not intentionally added to food but which is present in food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine (manufacture, processing, preparation, treatment, packing, packaging, transport or holding of food, or as a result of

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<sup>1</sup> SR 2010 No. 335

<sup>2</sup> OJ No. L320, 3.12.11, pg.15

<sup>3</sup> OJ No. L178, 10.7.2012, pg.1

<sup>4</sup> OJ No. L176, 6.7.2012, pg.43

<sup>5</sup> OJ No. L313, 13.11.2012, pg.14

<sup>6</sup> OJ No. L320, 3.12.2011, pg.18

<sup>7</sup> OJ No. L37, 13.2.93, pg.1

environmental contamination). Extraneous matter, such as, for example, insect fragments, animal hair, etc., is not covered by this legislation. There are more specific measures controlling mycotoxin contamination in food, as well as those chemicals that might migrate from contract materials and those that are radioactive, and which is currently laid down in other European legislation.

- 4.2 Maximum levels of chemical and other contaminants are therefore, set at defined levels that are reasonably achievable by following good agricultural and manufacturing practices and taking into account the toxicity of the contaminant in relation to the level of consumption of the affected foodstuff. In the case of contaminants which are considered to be genotoxic carcinogens, or in cases where current exposure of the population, or of vulnerable groups in the population, is close to or exceeds the tolerable level of intake, maximum levels are set as low as reasonably achievable (ALARA). This approach ensures that food business operators apply measures to prevent and reduce contamination as far as possible in order to protect public health. For the manufacturing of foods for infants and young children, a vulnerable group, the authorities establish the lowest maximum levels achievable through a strict selection of raw materials used.
- 4.3 Commission Regulations (EC) No's 124/2009 and 1881/2006 were introduced under the framework Regulation to protect public health and to ensure market unity, while complying with the principle of proportionality. The provisions and requirements of Commission Regulation 1881/2006 (and its predecessor Regulation (EC) No. 466/2001) have applied across the EU since April 2002.
- 4.4 Council Directive 76/621/EEC<sup>8</sup> as amended, relates to the fixing of the maximum level of Erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils and fats where the overall fat content exceeds 5%. The Directive limits the Erucic acid contents in food to no more than 5% calculated on the total level of fatty acids in the fat component and allows Member States to apply Erucic acid limits to foods with an overall fat content of 5% or less. This discretion has been used in the case of foods aimed at infants or young children, where the Erucic acid limit is applied to all those foods, not just those which contain more than 5% oils and fats. The Food Standards Agency (FSA), in consultation with the Department of Health, considers this lower limit provides an additional safety measure for this vulnerable consumer group.
- 4.5 The Mineral Hydrocarbons in Food Regulations (Northern Ireland) 1966<sup>9</sup> (purely national Regulations) are based on science which is now out of date. In addition the scope of the Regulations is too broad. By generally banning the sale or import of any food containing mineral hydrocarbons, the legislation has the unintended effect of banning the presence of residues of mineral hydrocarbons, which could be tolerated by EU contaminants legislation.

## **5. Parity or Replicatory Measure**

- 5.1 This Rule applies to Northern Ireland only. Parallel legislation is being made in England, Scotland and Wales.

## **6. European Convention on Human Rights**

- 6.1 As this Rule is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

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<sup>8</sup> OJ No. L202, 28.7.1976, pg.35

<sup>9</sup> SR 1966 No. 200

## 7. Policy background

- What is being done and why

- 7.1 The presence of contaminants, such as nitrate, coccidiostats and histomonostats, in foods can have a detrimental impact on consumer health. Consumers are unable to assess the risk from contaminants present in their foods and therefore, are unable to make fully informed choices about such risk. Providing for the execution and enforcement of the new EU Regulations provides for the continuation of consumer protection against exposure from such contaminants, which could carry serious long term and unacceptable risk to consumer health, particularly amongst vulnerable people.
- 7.2 Commission Regulation 1881/2006 sets maximum levels for nitrate in leafy vegetables; in some cases, despite developments in good agricultural practices, the maximum levels are exceeded.
- 7.3 Despite the progress achieved to reduce the presence of nitrate, it has not been possible to consistently achieve levels below the current maximum levels for nitrate in lettuce and fresh spinach in various regions of the EU. This is primarily as the result of the climate and in particular the light conditions which are a determining factor in the presence of nitrate in spinach and lettuce, and which cannot be managed or changed by the producer. Commission Regulation (EU) No. 1258/2011 sets higher, more achievable levels than those initially set for lettuce and spinach across the EU; it also, for the first time sets maximum levels for rocket, where a risk has been identified.
- 7.4 Coccidiostats and histomonostats are veterinary medicines authorised for use in animal feeds. Because of concern about the possible carry-over into batches of feed that are not intentionally formulated with coccidiostats or histomonostats, it has been considered necessary to introduce legislation at EU level limiting the permissible amount of coccidiostats and histomonostats carried-over into feed, in order to reduce the resulting residue into food from non-target animals.
- 7.5 Commission Regulation 124/2009, which sets maximum levels for the presence of coccidiostats and histomonostats in food as the result of the unavoidable carry-over (also known as cross-contamination into non-target feed), has recently been amended by Commission Regulation (EU) No. 610/2012 as regards the provisions for Lasalocid Sodium, Maduramicin, Nicarbazin and Diclazuril.
- 7.6 Council Directive 76/621/EEC as read with Commission Directive 80/891/EEC<sup>10</sup> (methods of analysis for determining Erucic acid levels) prescribes the levels for Erucic acid that are permissible in oils and fats for human consumption and in foodstuffs containing added oils and fats. Directive 76/621/EEC was last amended by Council Regulation (EC) No. 807/2003<sup>11</sup>. The provisions of Directive 76/621/EEC are currently implemented by The Erucic Acid in Food Regulations (Northern Ireland) 1977<sup>12</sup> and were last amended by the Erucic Acid in Food (Amendment) Regulations (Northern Ireland) 1982. The proposed Contaminants in Food Regulations (Northern Ireland) 2013 will revoke and remake the provisions currently contained in the 1977 Regulations as amended and will maintain the position that limits apply to foods for placing on the market for consumption by the final consumer. Consignments and deliveries to manufacturers for the purpose of

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<sup>10</sup> OJ Ref, L254, 27.9.1980, pg.35

<sup>11</sup> OJ Ref, L122, 15.5.2003, pg.36 – Adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (unanimity)

<sup>12</sup> SR 1977 No.135

manufacturing business or to a caterer for their business are thus not the subject to the requirements.

- 7.7 The proposed Regulations will also revoke The Mineral Hydrocarbons in Food Regulations (Northern Ireland) 1966. The FSA has considered a number of options for amending/updating the legislation, taking account of the recent EFSA opinion on mineral oils and have consulted major trade associations about the current uses of mineral hydrocarbons. From the information received by the FSA, there is no use of mineral hydrocarbons in the UK food industry. There is also little use of these substances for other processing functions; thus, the FSA considers that the Mineral Hydrocarbons Regulations no longer serve any practical function and that an equivalent level of public health protection is achieved by newer legislative controls on mineral hydrocarbons in EU legislation on food additives and contaminants, and by the General Food Law Regulation.
- 7.8 The 2013 Regulations continue to use ambulatory references; at present the ambulatory references in the current 2010 Contaminants Regulations only apply to the Annexes of Commission Regulation 1881/2006. It is being proposed to extend the ambulatory references to include both Articles as well as Annexes of Regulation 1881/2006, as sometimes the technical changes are found in the former and latter. Extending the use of ambulatory reference will avoid the need to introduce a new SI each time any of these Annexes or Articles is updated. Ambulatory references will also include the Articles/Annexes of Commission Regulation 124/2009 and Commission Directives 76/621/EEC and 80/891/EEC on Erucic acid.

## **8. Consultation outcome**

### ***Informal Public Consultation***

- 8.1 The FSA has consulted consistently with all its stakeholders, including industry trade bodies; enforcement authorities, consumer organisations; research laboratories and others with an interest in chemical contaminants legislation; during negotiations with the Commission and other Member States on the amendments to Regulation 1881/2006 and the new Regulation setting limits for nitrate.
- 8.2 The FSA held two meetings with stakeholders and industry trade bodies in January and October 2011, informing businesses on the EU negotiations and plans for implementation of the maximum limits for nitrate in spinach, lettuce and rocket. The meetings highlighted potential compliance issues with rocket, for which stakeholders agreed to provide data on the number of businesses likely to be affected by the new nitrate limits for rocket.
- 8.3 Comments received from stakeholders highlighted various cost to business as a result of seasonal imports, mainly during the winter months from other EU Member States (notably Spain, Italy, and France). Stakeholders also commented that reference is required to the sampling methodology in any guidance issue and a clarification on the methodology of analysis, as there are differences in the techniques used by different laboratories, which will affect the results.

### ***Formal Public Consultation***

- 8.4 The Food Standards Agency in Northern Ireland conducted a formal public consultation from 12 April and 8 July 2013 on a draft of the proposed S.R and the associated draft Impact Assessment. One response was received in Northern Ireland.

8.5 A full summary of the comments received in response to the consultation will be published on the FSA's website.

## **9. Equality Impact**

9.1 These regulations will apply in equal measure to all Section 75 groups. It is not expected that any of these changes will impact differentially across any of the section 75 groups.

## **10. Guidance**

10.1 Existing guidance will be updated to take into account the new revised limits for nitrate and coccidiostats and histomonostats. The revised guidance will be published on the FSA website at [www.food.gov.uk/policy-advice/](http://www.food.gov.uk/policy-advice/)

## **10. Impact**

10.1 As set out in the Impact Assessment, the proposed Regulations will affect retailers and wholesalers, importers, primary producers and any food business operators (FBOs) responsible for placing on the market products covered by the nitrate Regulation. Retailers and wholesalers that sell green leafy vegetables will need to be aware of the revised/new limits and will incur a small familiarisation cost.

10.2 For producers of rocket, the nitrate Regulation introduces new limits for nitrate and these producers will also incur a cost for familiarisation; the new limits for nitrate in lettuce and spinach have been relaxed; producers in this sector are already aware of the existing limits, as well as the changes to these limits. Therefore, producers of lettuce and spinach will incur costs for familiarisation, but these are expected to be minimal. The levels for nitrate in rocket were raised during EU negotiations in response to comments from industry during informal consultation. Also during informal consultation with stakeholders, potential compliance costs were identified as a result of introducing the new nitrate limits for rocket. However, to date, we have not been able to monetise this potential impact with stakeholders. We will continue to engage with the relevant stakeholders post-implementation and will review the policy as appropriate.

10.3 Feed manufacturers will also incur a small familiarisation cost associated with the new limits for the presence of coccidiostats and histomonostats, resulting from the carry-over of these substances to non-target feed introduced by Regulation 610/2012. There may also be a cost for sampling and analysis.

10.4 There is no particular impact on charities or voluntary bodies, rural areas or on members of the ethnic communities of any particular racial group that can be identified. No comments were received from such bodies on the effects of the proposal on them.

## **11. Regulating small business**

11.1 The rule will apply to all businesses, small and large.

## **12. Monitoring & review**

### ***Monitoring***

12.1 The FSA will work with District Councils where problems arise or suspected infringements of the rule arise. The effectiveness of the rule will be also be monitored via general feedback from Industry and Enforcement Authorities.

12.3 The European Commission investigates whether limits should be set for additional contaminants and also reviews the maximum limits for those contaminants currently in the legislation and the foods that are subject to control. Such limits may be moved upwards or downwards in the light of on-going monitoring and of advances in scientific knowledge within the EU as a whole.

### **13. Contact**

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